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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,615	06/07/2006	Stephen William Eason	478.1081	3149
23280 7590 07/07/2010 Davidson, Davidson & Kappel, LLC 485 7th Avenue 14th Floor New York, NY 10018				
EXAMINER				
BLIZZARD, CHRISTOPHER JAMES				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,615

Applicant(s)

EASON ET AL.

Examiner

CHRISTOPHER BLIZZARD

Art Unit

3771

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 64-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 64-84 is/are rejected.
- 7) ☒ Claim(s) 65-70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to amended claims filed 2/3/10. As directed claims 1, and 64 were amended, claims 36-63 were cancelled and claim 84 was added. Therefore, this application currently has claims 1-35 and 64-84 pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5, 8-13, 28-30, 31, 64 and 72 rejected under 35 U.S.C. 102(b) as being anticipated by Piper (5,533,502).

4. Regarding claims 1-3, Piper discloses an inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation (column 4, lines 40-58), a mouthpiece (52) through which medicament is inhaled and acts an arm of a pivotally mounted actuator that sequentially moves each blister into alignment with a blister piercing member (column 2, lines 42-55), due to the blister being pivoted into position by the actuator the lid of a blister is caused to be pierced by the blister piercing member such that an airflow through the

blister entrains a dose of medicament to be inhaled (column 2, lines 56-67; column 3, lines 1-7).

5. Regarding claims 4 and 5, Piper discloses the blister piercing member containing two discrete piercing heads (60, 62) depending from one side of the arm and extending through an aperture in the housing in a closed position, in which the arm is against the housing, piercing a lid of a blister (fig. 4).

6. Regarding claims 8 and 9, Piper discloses openings in the arm corresponding to the piercing heads (60, 62) that form an airflow inlet and an airflow outlet in the blister in communication with the mouthpiece (52) (fig. 4).

7. Regarding claims 10 and 11, Piper discloses an inhaler wherein the mouthpiece includes a primary chamber having an outside air inlet (70) in communication with an airflow inlet (fig. 4) and a secondary chamber separated by an internal wall and in communication with an airflow outlet (fig. 4).

8. Regarding claims 12, 13, and 72, Piper discloses an air bypass aperture (fig 4 around #40) communicating with the primary and secondary chambers (fig. 3) and creating turbulence to entrain medicament in airflow.

9. Regarding claim 28-30, Piper does not disclose the inhaler being formed of any moulded parts, and thus inherently does not have to be comprised of more than five, six, or nine moulded parts.

10. Regarding claim 31, Piper discloses the cover (12) being made of a transparent material (column 6, lines 48-51).

11. Regarding claim 64, Piper discloses the inhaler wherein a indexing mechanism comprises a blister strip locator chassis defining a path for a strip of blisters past the blister piercing member (column 6, lines 63-67) (fig. 7).
12. Claims 1, 14-16, 18-20, 32-35, 71, and 73-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Brunnberg (6,880,555).
13. Regarding claims 1, 14 and 15, Brunnberg discloses an inhaler comprising a housing to receive a plurality of blisters (78, 80) with puncturable lids containing doses of medicament for inhalation and an actuator that pivots about an axis (72) that acts as an indexing mechanism that moves a blister in alignment with a blister piercing member with an indexing wheel (70) and causes the lids to be pierced to generate an airflow through the blister to entrain (column 6, lines 35-67; column 7, lines 1-7).
14. Regarding claims 16, 18-20, 73-75 and 77, Brunnberg discloses the inhaler wherein rotation of the actuator (236) in one direction moves the blister into alignment and movement of the actuator in the other direction is operable to puncture the lid of the blister (column 6, lines 35-67; column 7, lines 1-7). The actuator is connected to a cap which rotates with the actuator and covers the mouthpiece (202) in a closed position and reveals it for use in an open position (figs. 11, 12).
15. Regarding claims 32-35, 79 and 81 Brunnberg discloses a method of use of the inhaler above wherein inhaling through the mouthpiece (202) generates an airflow through the blister and entrains a dose of medicament into the user's airway (column 6, lines 46-48).

16. Regarding claim 71, Brunnberg discloses the piercing member comprising a discrete piercing module (20).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piper (5,533,502).

19. Regarding claims 6 and 7, Piper discloses an inhaler with a piercing head with a primary (58) and secondary (60) cutting element each with a pointed tip (fig. 4), but does not disclose a pair of secondary cutting elements extending laterally across each end of the primary cutting element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the inhaler of Piper having a plurality of secondary cutting elements, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

20. Claims 17, 76, 78, 80, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunnberg (6,880,555).

21. Regarding claims 17, 76, 78, 80, 82 and 83, Brunnberg discloses the claimed inhaler except for wherein the actuator aligns the blister with the blister piercing member and punctures the lid of the blister while being rotated in the same direction. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to position the feed wheel (242) to align the blister with the blister piercing member during closing of the actuator arm, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

22. Claims 21-27 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunnberg (6,880,555) as applied to claim 1 above, and further in view of Widerstrom (6,698,425).

23. Regarding claims 21-23, Brunnberg discloses the claimed device except for a chamber to receive used blisters. Widerstrom teaches an inhaler in which used blisters being stored in a chamber to or exiting the housing through slot (figs. 6 and 8) (column 6, lines 8-10). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the inhaler of Brunnberg with a used blister handling system as taught by Widerstrom in order to provide the advantage of being able to tell how many blisters have been used.

24. Regarding claims 24-27, the combination of Brunnberg and Widerstrom teach the claimed inhaler wherein Widerstrom teaches incorporating a coiled strip of blisters (fig.1a) that have perforations to enable tearing off used blisters (column 3, lines 49-51). The strip contains more than 30 blisters (fig. 1b) and may contain a dose payload between 10 and 25mg (column 7, lines 20-43).

25. Regarding claims 84, the combination of Brunnberg and Widerstrom teach the claimed inhaler wherein Widerstrom teaches the blisters being on a coil strip that is

pivoted around to unwind the coil in order for the blisters to be sequentially aligned with a blister piercing member (fig. 1a, fig. 1b).

Allowable Subject Matter

26. Claims 65-70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

27. Applicant's arguments filed 2/3/10 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 1-72 have been considered but are moot in view of the new ground(s) of rejection. Applicant's argument that Brunnberg does not teach an inhaler that has an actuator that is operable, in response to rotation of the cap, to cause the blister piercing member to puncture the lid of an aligned blister is not persuasive because the rotation of the cap does cause the blister to be pierced in that if the cap was not rotated then the cocking mechanism for the breath actuation mechanism would not be cocked and the blister piercing member would not pierce.

Conclusion

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday-Friday, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3771

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761